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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|--------------------------|---------------------|------------------|
| 10/814,777 | 03/30/2004 | Yenamandra Venkateswarlu | 03108/0201123-US0 | 4938 |
| 7278 | 7590 | 09/27/2006 | EXAMINER | |
| DARBY & DARBY P.C. | | | | DESAI, RITA J |
| P. O. BOX 5257 | | | | ART UNIT |
| NEW YORK, NY 10150-5257 | | | | PAPER NUMBER |
| | | | | 1625 |

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/814,777 | VENKATESWARLU ET AL. | |
| | Examiner | Art Unit | |
| | Rita J. Desai | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 7/7/06.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 2 is/are allowed.
- 6) Claim(s) 1 and 3-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 9/04.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 7/7/06 is acknowledged. The traversal is on the ground(s) that invention I and II are related as product and process of making the product and that the process as claimed cannot be used to make materially different products. This is not found persuasive because the process can just differ in the starting material and that does not make it different. It can be very obvious over other processes of extracting.

Applicants also argue that the product can be made by a different process is not correct as there are number of substances exacted and the only difference is the starting material, thus the process is an obvious variant.

There are several different ways of extracting and making the compounds from natural products. The search is burdensome to the PTO.

The requirement is still deemed proper and is therefore made FINAL.

It should be noted however if the compounds of the elected group are found to be allowable then the process of making and method of treating limited to the scope of the allowed claims will be rejoined.

The compounds are found to be allowable over the prior art hence the process claims 4-10, 24-37 process of making, and claims 15, 16, 47 drawn to complex compositions, 17-19, 38-46 drawn to a method of treating are being rejoined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 3-14, 24-37 does not recites the limitation "R1, R2, R3 and its variables".

Claims 2-3, have these variables and are dependent from claim 1. There is insufficient antecedent basis for this limitation in the claim. Also the term (n) is not in claim 1.

Claim1, 3-10, 24-37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" is not clear as to what compounds were included.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 16 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to compounds extracted from an ascidian with different "R" groups. The claims are drawn to a complex compositions with other ingredients. In the specifications on page 11 describes the following.

comprising a first chemotherapeutic agent including timchenduramine or a derivative thereof and a second-therapeutic agent. The second therapeutic agent is not tiruchenduramine or a derivative thereof. These compositions are effective to suppress postprondial hyperglycemia in a subject. Various classes of therapeutic agents, including alkylating agents, antimetabolites, vinca alkaloids, antibiotics, cytokines, growth factors, non-steroidal anti-inflammatory drugs, such as aspirin, may be used in the composition.

The only drug identified is aspirin. There is no description of antimetabolites, vinca alkaloids, cytokines , growth factors, alkylating agents.

There is no structure given to these group. The specification gives no guidance to one of ordinary skill in the art which compounds these may be. The specification does not define the compound in these categories. The same is true for all the choices recited at page 11. T Note all the groups recited for this choices have functional language. The functional groups includes plethora of compounds, which has this functional moieties.

The expression "antimetabolites, vinca alkaloids, cytokines , growth factors, alkylating agents ". without i.e. partial or complete structure does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited

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without any correlation does not meet the written description requirement for the expression "antimetabolites, vinca alkaloids, cytokines , growth factors, alkylating agents.

" as one of ordinary skill in the art could not recognize or understand the structure from the mere recitation of the function which agents or compounds are included. Claims employing functional language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds.

Claims 14, 17-19, 38-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to compounds that can treat diabetic disorder. The specification on page 1 states vascular complications of diabetes melitus. Alpha (or) glucosidases are a group of. inhibltors target the alpha .glucosidasc such as sucrase, maltase, glycoamylase dextranase and isomaltases and to reduce Postprondial hyperglycemia primarily by interfering with the carbohydrate digesting enzymes and delaying glucose absorption. '

The present invention relates to a novel chemical compound and more

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particularly, the β 3-carboline guanidine alkaloid, tiruchenduramine (1) and derivatives (2-20), derived from an ascidian. These compounds, are useful as Glucosidase Inhibitors.

The specification gives no guidance to one of ordinary skill in the art that these disorder can be treated. The specifications are devoid of any tests and data that these compounds do indeed treat diabetic disorders.

The expression “diabetic disorder”, does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited without any correlation does not meet the written description requirement, as one of ordinary skill in the art could not recognize or understand which diseases /disorders are treated by the mere recitation of the function. Claims employing functional language at the point of novelty, such as applicants’, neither provide those elements required to practice the inventions, nor “inform the public” during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of diseases and applicants claimed expression represents only an invitation to experiment regarding possible treatments.

So not only do applicants have no description for the complex compositions, there is no description for the treatment also.

Applicants have no example or guidance that these would indeed treat the disorders.

In the pharmaceutical art, which is highly unpredictable applicants need to show “more” that the compounds do indeed treat diabetic disorders.

It is noted that the pharmaceutical art is unpredictable , requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18(CCPA

1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. The level of unpredictability is in the art is very high.

Conclusion

The claims 1, 3-47 are not found to be allowable.

Claim 2 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai

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Primary Examiner
Art Unit 1625

R.D.
September 21, 2006

R.D. Desai
9/22/06